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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,766	07/15/2003	Christopher Charles Abney	PR60153US1	8793

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EXAMINER

STITZEL, DAVID PAUL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/619,766	<b>Applicant(s)</b> ABNEY ET AL.	
	<b>Examiner</b> David P. Stitzel, Esq.	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*pd*

## OFFICIAL ACTION

### *Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-17, 18, 23, 30-32, 36-53 and 57-58 are drawn to a pharmaceutical composition and a controlled release solid dosage form containing said pharmaceutical composition, wherein said pharmaceutical composition comprises: lithium carbonate; a pharmacologic excipient; a dissolution rate stabilizer; and a release agent. The aforementioned pharmaceutical composition is classified in class 514, subclass 960.
- II. Claims 19-22, 27-29 and 54-56 are drawn to a method of making a pharmaceutical composition containing lithium carbonate and a process for preparing a controlled release solid dosage form containing said pharmaceutical composition, as classified in class 424, subclass 451.
- III. Claims 24-26, 33-35 and 59-60 are drawn to a method of using a lithium carbonate pharmaceutical composition for the treatment of bipolar disorder and manic depression, as classified in class 252, subclass 62.61.

Inventions I and II are related as a product and a method of making said product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another materially different product; or (2) that the product as claimed can be made by another materially different process (MPEP § 806.05(f)). In the instant case, a lithium carbonate composition can be prepared using methods that are materially different from the method claimed in Invention II. For example, instead of preparing a lithium carbonate

composition in accordance with the method claimed in Invention II, a lithium carbonate composition can alternatively be prepared by a materially different processes, such as dragee-making or entrapping, as described in paragraph [0070] of Pre-Grant Publication Number US 2005/0181070.

Inventions I and III are related as a product and a method of using said product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) that the method for using the product as claimed can be practiced with another materially different product; or (2) that the product as claimed can be used in another materially different method of using said product (MPEP § 806.05(h)). In the instant case, the lithium carbonate composition as claimed in Invention I can be utilized in methods that are materially different from the method claimed in Invention III. For example, as opposed to treating bipolar disorder and manic depression, a lithium carbonate composition may alternatively be utilized in the removal of calcium contaminants from brine during the production of high purity lithium hydroxide, as described in the Brown '713 patent (abstract).

Inventions II and III are distinct as a method of making a product and a method of using said product. The inventions are distinct because they have different modes of operation, different functions, or different effects (MPEP § 808.01). In the instant case, the method of making a lithium carbonate composition as claimed in Invention II is patentably distinct from the method of using a lithium carbonate composition for the treatment of bipolar disorder and manic depression as claimed in Invention III.

Because these inventions are distinct for the reasons given above and the search required for Groups I, II and III are not required for Groups, II & III, I & III, and I & II, respectively, restriction for examination purposes as indicated is proper.

***Conclusion to Restriction Requirement***

The examiner has required restriction between product, methods of making and methods of using claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn methods of making and methods of using claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Methods of making and methods of using claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. If claims are added after the election, Applicants must explicitly indicate which claims are readable upon the elected species. See MPEP § 809.02(a). Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

***Applicants are advised that a fully responsive reply to this requirement must include an explicit identification of the specific species that is elected consonant with this requirement, and a listing of all claims, including any claims subsequently added thereto, which are readable upon the elected species. Generic claims that are not listed by the Applicants as being readable upon the elected species will be withdrawn from prosecution on the merits. An argument that a claim is allowable or that claims are not generic is considered nonresponsive unless accompanied by an election of a specific species. See 37 C.R.R. § 1.143. Should***

Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other inventions.

Upon the allowance of a generic claim, Applicants will be entitled to a consideration of claims that are directed to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined methods of use claims will be withdrawn, and the rejoined methods of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and methods of use claims may be maintained. Withdrawn methods of use claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the methods of use claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition

against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named Inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

#### ***Contact Information***

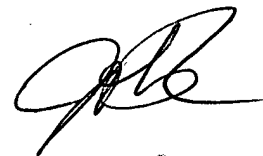
A telephone call was made to Mr. Robert Smith, Esq. on Thursday, September 22, 2005 to request an oral election. However, due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See, MPEP § 812.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The examiner can normally be reached on Monday-Friday, from 7:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached at 571-272-0887. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see <http://pair-direct.uspto.gov>. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*David P. Stitzel, Esq.*



JOHN PAK  
PRIMARY EXAMINER  
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